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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/155,676 | 01/04/1999 | DAVID WALLACH | WALLACH=21 | 8997 |

1444 7590 11/20/2001

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EXAMINER

EPPS, JANET L

ART UNIT PAPER NUMBER

1635

DATE MAILED: 11/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,676

Applicant(s)

WALLACH ET AL.

Examiner

Janet L Epps

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16, 20-22, 30, 43-60 and 62-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16, 20-22, 30, 43-60, 62-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 13-16, 20-22, 30, 43-60, and 62-68 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid molecules according to SEQ ID NO: 1, 4, and 6 which encode polypeptides which bind Traf2 and either inhibit or increase the expression NF- κ B, does not reasonably provide enablement for any other nucleic acid sequences encoding polypeptides which bind Traf2 and either inhibits and increases the expression of NF- κ B. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons of record set forth in the Official Action mailed 5-08-2001.

Applicant's arguments filed 9-10-2001 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by way of amending the instant claims by replacing the term "modulate" with the phrase: "either inhibits or increases." Applicants have simply amended the claims to recite the definition of the term "modulate," as stated in the prior Official Action Applicants are not enabled for the broad genus of nucleic acid molecules encompassed by the claimed invention, wherein said genus includes nucleic acid molecules of unknown sequence. Although applicants provide an assay for isolating nucleic acids which encode polypeptides that bind Traf2 and either inhibits or increases the activity of NF- κ B, without knowledge of the all the structures of the nucleic acid molecules one of skill in the art

Art Unit: 1635

would have to resort to trial and error experimentation in order to determine the structures of all possible nucleic acids encoding polypeptides having the desired function.

Furthermore, as stated in the prior official action, there is no indication of what specific amino acid substitutions, deletions, insertions, or amino acid modifications must be made to the polypeptides of the instant invention in order to isolate those polypeptides with the claimed activity, specifically those which modulate NF- κ B activity and bind TRAF2. Applicants have merely provided an invitation to experiment, without providing unambiguous instructions on how to make the polypeptides of the present invention.

Although, it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a polypeptide's structure and function from mere sequence data remains an elusive task. For example, while polypeptides that differ markedly have been shown to have similar function, small changes in polypeptide structure have often inexplicably resulted in complete loss of function. Where the art is unpredictable, more guidance is required. *In re Fisher*, 166 USPQ 18, n.5 (CCPA 1970). Considering the scope of the claims, the degree of unpredictability in the art, the amount of experimentation required and the lack of guidance presented, the experimentation left to those skilled in the art is undue.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

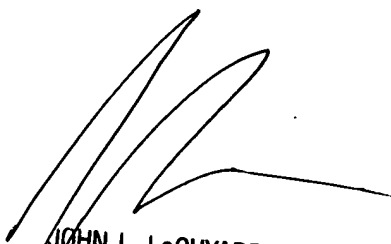
Art Unit: 1635

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps
Patent Examiner
November 15, 2001



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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